Section 4. 510(k) Summary

APR 30 2008

General Provisions

Submitter's Name and Address:	EKOS Corporation 11911 North Creek Parkway South Bothell, WA 98011
Contact Person:	Jocelyn Kersten 425-415-3132 425-415-3102 (fax) jkersten@EKOSCORP.com
Classification Name:	Catheter, Continuous Flush (KRA)
Regulation Number:	21 CFR §870.1210
Common or Usual Name:	Continuous Flush Catheter
Proprietary Name:	EndoWave Infusion System
Name of Predicate Device:	EndoWave Infusion System
510(k) Reference No.:	K072507, K062508

Device Description
The system consists of a disposable infusion catheter with removable ultrasound core and an instrument that generates and controls the delivery of energy to the catheter. The infusion catheter contains multiple side holes distributed over the length of the treatment zone. The ultrasound core contains up to 30 ultrasound elements, evenly spaced over the treatment zone. Thermal sensors in the treatment zone monitor catheter temperature.

Intended Use
The EndoWave Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Summary of Technological Characteristics
The device modification described in this notification does not affect the technological characteristics for the EndoWave Infusion System.

Test Summary
Testing confirmed the revised acoustic protocol remains safe and the ultrasound core will operate as required with the new protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

EKOS Corporation
c/o Ms. Jocelyn Kersten
Vice President, Quality Assurance, Regulatory and Clinical Affairs
11911 N. Creek Pkwy S
Bothell, WA 98011

Re: K080392
Trade Name: EndoWave™ Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: March 27, 2008
Received: March 31, 2008

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080392

Device Name: EndoWave Infusion System

Indications For Use: The EndoWave Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080392